MAR 1 2002

K02D340

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name: Guidant Corporation
Vascular Intervention

Submitter's Address: 26531 Ynez Road
Temecula, CA 92591

Telephone: (909) 914-4581
Fax: (909) 914-0339

Contact Person: Jennifer Pae Riggs

Date Prepared: January 25, 2002

Device Trade Name: HI-TORQUE WHISPER™ LS and MS

Device Common Name: Guide Wire

Device Classification Name: Guide Wire Catheter

Device Classification: Class II

Summary of Substantial Equivalence:

The design, materials, method of delivery and intended use features of the HI-TORQUE WHISPER™ LS and MS Guide Wires are substantially equivalent with regard to these features in their predicate device, the HI-TORQUE WHISPER™ LS and MS Guide Wires (K002206, August 24, 2000 and K013092, December 13, 2001).

Device Description:

The HI-TORQUE WHISPER™ LS and MS Guide Wires with Hydrocoat Hydrophilic Coating are guide wires with a 0.014" diameter and available in 175 cm and 190 cm extendable lengths and a 300 cm exchange length. The proximal end of the 175 cm and 190 cm models are tapered to fit into the hypotube portion of the ACS DOC® Guide Wire Extension. This enables the physician to extend the working length of this guide wire to facilitate catheter exchanges. The wires are constructed with a stainless steel core wire. The proximal section of the core wire has a constant diameter and the distal core

segment tapers in diameter to the tip. Attached to the distal core is a tip coil that provides radiopacity. The distal 30 cm of the core wire is jacketed with a polyurethane coating that is coated with a hydrophilic coating. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE). The distal tips of the guide wires are available either as a straight tip that is shapeable or as a pre shaped "J".

Intended Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA) and compatible stent devices during therapeutic intravascular procedures.

Technological Characteristics:

Comparisons of the proposed and predicate device show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are identical or substantially equivalent to the currently marketed predicate device. The only change is the new tungsten material.

Performance Data:

The results of the verification testing demonstrate that the HI-TORQE WHISPER™ LS and MS Guide Wires meet the established acceptance criteria and performs in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during the testing program.

Conclusions:

The HI-TORQUE WHISPER™ LS and MS Guide Wires with the new material has the same intended use, technological characteristics, performance properties, identical sterilization and substantially equivalent materials. Therefore, there are no new safety or effectiveness issues. The HI-TORQUE WHISPER™ LS and MS Guide Wires with the new material are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2002

Ms. Jennifer Pae Riggs
Guidant Corporation
26531 Ynez Road
Temecula, CA 92591-4628

Re: K020340
HI-TORQUE WHISPER™ LS and MS Guide Wires with Hydrophilic Coating
Regulation Number: 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II (two)
Product Code: DQX
Dated: January 31, 2002
Received: February 1, 2002

Dear Ms. Riggs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

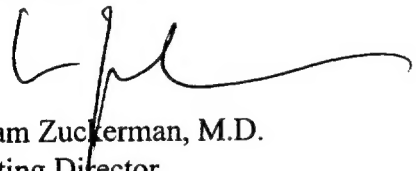
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MAR 1 2002

Indications for Use Statement

510(k) Number (if known) K020340

Device Name HI-TORQUE WHISPER™ LS and MS Guide Wires with Hydrophilic Coating

Indications for Use To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA) and compatible stent devices during therapeutic intravascular procedures.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

for Division of Cardiovascular & Respiratory Devices
510(k) Number K020340